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APPLICATION NO. 09/052,772	FILING DATE 04/22/99	FIRST NAMED INVENTOR ARIYASU	ATTORNEY DOCKET NO. ARIYASU-1
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WASHINGTON, DC 20004

EXAMINER KAUFMAN, C

ART UNIT 1846	PAPER NUMBER
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DATE MAILED: 06/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/063,778

Applicant(s)

ARIYASU ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 1998.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other:

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DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to hedgehog protein, classified in class 530, subclass 350.
- II. Claims 7-13 and 17-20, drawn to DNA and method of producing the protein by expression of the DNA, classified in class 536, subclass 23.1, and class 435, subclass 69.1.
- III. Claims 14-16 and 21-22, drawn to antibody, hybridoma and method of immunodetection, classified in class 530, subclass 387.1, and class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The DNA and recombinant method of protein production of Invention II is related to the protein of Invention I by virtue of the DNA encoding and method producing the protein. The DNA has utility for the recombinant production of the protein in a host cell, as recited in claim 17. Although the DNA and protein are related since the DNA encodes the specifically claimed protein and can be used in its production, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assays.

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The protein of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used for another and materially different method other than for production of the antibody and other than the method of Invention III, such as to assay or purify the natural receptor of the protein (as the protein is itself a ligand), or in assays for the identification of agonist or antagonists of the protein.

Likewise, the DNA of Invention II is related to the antibody of Invention III by virtue of encoding the cognate antigen. However, for the reasons in the preceding paragraph and because the nucleic acid cannot encode the antibody or be used in the method of Invention III, and the DNA can be used in a process materially different than the production of the protein, such as in a hybridization assay, the DNA and method of producing the protein are distinct from the antibody and methods of immunodetection. Further, the methods of Invention II and III use different process steps and compounds, and have different effects and functions.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, and the search required for each invention is not coextensive with another, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

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Claire M. Kaufman, Ph.D.



15 Patent Examiner, Art Unit 1646

June 9, 1999



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: **C. Kaufman**

ART UNIT: **1646**

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
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COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096-OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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